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DEKM:055

September 23, 1996

CERTIFICATE OF MAILING
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September 23, 1996
Date

David L. Parker

Assistant Commissioner for Patents
Washington, D.C. 20231

RE: **SN 08/113,561 "METHODS AND COMPOSITIONS FOR THE PRODUCTION OF STABLY TRANSFORMED, FERTILE MONOCOT PLANTS AND CELLS THEREOF"-- Adams *et al.***

Dear Sir:

Enclosed for filing in the above-referenced patent application are:

(1) Appellants' Reply to Examiner's Answer;

(2) Appendix A - Claims on Appeal;

(3) Amendment Under 37 C.F.R. § 1.116 regarding Claim 50;

(4) Petition Under 37 C.F.R. § 1.116, 1.127 and 1.181 regarding Claims 53 and 54;

(5) A return postcard to acknowledge receipt of these materials.

Please date stamp and mail this postcard.

Appellants believe that there are no fees required in connection with the filing of these documents. However, should any fees be deemed necessary under 37 C.F.R. §§ 1.16 to 1.21 for any reason relating to the enclosed materials, the Assistant Commissioner is authorized to deduct said fees from Arnold, White & Durkee Deposit Account No. 01-2508/DEKM:055/PAR.

Appendix A attached to enclosed the Reply Brief reflects the claims under appeal as they would read if both the Amendment Under 37 C.F.R. § 1.116 regarding Claim 50 and the Petition Under 37 C.F.R. § 1.116, 1.127 and 1.181 regarding Claims 53 and 54 were granted. In the event that either the Amendment or Petition are not granted, Appellants will submit an amended Appendix A to accurately reflect the status of the appealed claims.

Respectfully submitted,

David L. Parker
Reg. No. 32, 165

Attorney for Appellants

PAR/NAK:kcr
Enclosures

38
11/7/96

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: Adams *et al.*	§	
	§	Group Art Unit: 1804
Serial No.: 08/113,561	§	
	§	Examiner: G. Benzion
Filed: August 25, 1993	§	
	§	Atty. Dkt.: DEKM:055/PAR
For: METHODS AND COMPOSITIONS FOR THE PRODUCTION OF STABLY TRANSFORMED, FERTILE MONOCOT PLANTS AND CELLS THEREOF	§	

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September 23, 1996
Date

David L. Parker

APPELLANTS' REPLY TO EXAMINER'S ANSWER

Assistant Commissioner for Patents
ATTN: BOX AF
Washington, D.C. 20231

Sir:

Appellants provide the following Reply to the Examiner's Answer, including a reply to the new points of argument raised in the pending § 103 rejections and a response to the new ground of rejection under 35 U.S.C. § 112, second paragraph.

A. The Examiner's Answer Raises New Points of Argument With Regard to Motivation

The Examiner argues that the **motivation** to substitute known genes into maize plants is provided by: "1) the desire to obtain the agronomic benefits for which each gene type is known and 2) from the expectation provided by Goldman *et al.* that the modified plant will, in fact, demonstrate that disclosed agronomic benefit." (Answer at page 4, last paragraph) This represents a new point of argument not raised in the earlier Office Actions.

Although the question of motivation was mentioned in passing in the Advisory Action mailed on 7/27/95 (page 4), it was only in the Examiner's Answer that this point of argument was fully developed and applied to the reference of Goldman *et al.* (Answer, pages 4, 6-9). Appellants submit that the Examiner's comments addressed to the motivation of a skilled practitioner form the core of the Answer. The question of motivation is addressed in each part of the Answer's Response to Arguments. At the very least, the motivation issue forms a new point of argument in terms of the scope of argument. Appellants reiterate that motivation has not previously been addressed with regard to the Goldman reference. Appellants therefore request that in order to avoid prejudicing their case, the Examiner enter this Reply concerning the issue of motivation.

1. None of the Prior Art Cited by the Examiner Provides a Motivation to Make and Use the Instant Invention.

As argued in Appellants' Brief, in order for a prior art teaching to obviate an invention, it must be shown that the teaching contains: 1) detailed enabling methodology for practicing the claimed invention; 2) a suggestion for modifying the prior art to practice the claimed invention;

and 3) evidence suggesting that the invention would be successful. *In re O'Farrell*, 7 U.S.P.Q. 2d 1673, 1680 (Fed. Cir. 1988). The requirement for a suggestion for modifying the prior art to practice the claimed invention goes to the issue of motivation raised in the Examiner's Answer.

In the more recent case of *In re Vaeck*, 20 U.S.P.Q.1438 (Fed. Cir. 1991), the Federal Circuit stated that a *prima facie* case of obviousness required that two things be shown: 1) the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition; and 2) the prior art must demonstrate a reasonable expectation of success of the invention.

The Examiner takes the position that since the genes specified in the appealed claims are known to confer specific traits on other plants, corn plants genetically engineered to incorporate these genes are *prima facie* obvious. The **motivation** to introduce these genes into corn is said to arise out of references by Goldman and Lundquist, which set forth several traits and exemplary genes that one might introduce into corn.

These references teach fertile, transgenic corn generically, as well as a variety of transgenic corn expressing a particular trait or bearing a particular gene. (See Answer at bottom of page 7) Neither of these references, alone or in combination with secondary references, teach or suggest transgenic corn bearing the specific genes set forth in the appealed claims. They therefore provide no **motivation** for preparing transgenic corn bearing these particular genes and contain no evidence that such an undertaking would be successful under the test of *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). (See Appellants' Brief at pages 12-15)

2. An Earlier "Generic" Teaching does not Provide Motivation to Make and Use a Later Species within that Genus.

In that Appellants' claims are directed to a new structural chemical entity, a *prima facie* case of unpatentability requires that the prior art suggest *the specific claimed compound* to a person of ordinary skill in the art. Even if the *general idea* of the claimed compound and its function may have been obvious from the prior art, the particular combination claimed is not obvious, since it is not disclosed in any of the cited prior art references. Until the claimed combination was disclosed in the present application, it was unlikely that one of ordinary skill in the art would have contemplated it. "What cannot be contemplated or conceived cannot be obvious." *In re Deuel*, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995).

In *Amgen Inc., v. Chugai Pharmaceutical Co. Ltd.*, 18 U.S.P.Q. 1016 (Fed. Cir. 1991), the Federal Circuit said that conception of a chemical compound does not occur unless one has a mental picture of the structure of the chemical, or is able to define the compound so as to distinguish it from other materials . It is not sufficient to define it solely by means of its biological property, because *such an alleged conception simply constitutes a wish to know the identity of any material with that biological property.*

The reference in Lundquist *et al.* to "all DNA" which provides desired biological traits in corn plants is simply a wish to know the identity of a specific chemical composition with that biological property. Lundquist *et al.* teaches the general method, but not the combination claimed in the instant invention. Similarly, the reference by Goldman *et al.* to "heterologous genes which confer agronomically significant traits on plants" provides only a vague generic

teaching that fails to teach the specific combination claimed in the instant invention.

The Answer states that some of the traits recited in Lundquist are the same as the traits sought with the distinct genes set forth in the appealed claims. But, "A *general* incentive does not make obvious a *particular* result.... The fact that one can conceive a general process in advance for preparing an *undefined* compound does not mean that a claimed *specific* compound was precisely envisioned and therefore obvious." (emphasis added) *In re* Deuel, 34 U.S.P.Q.2d at 1216. In the present case, all that Goldman or Lundquist teach is a generic result, not the particular combination and grouping of DNA set forth in the appealed claims. The cited prior art discloses various traits desirable for corn plants and certain genes that code for the traits mentioned. The prior art therefore encompasses the claimed combination, but does not disclose the particular combination of genes and gene elements in the transgenic corn plant as claimed.

The fact that the genes disclosed in Goldman and Lundquist and the genes used in the claimed combination have common utility is of no consequence in view of *In re Jones,* 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992). In *Jones*, a claim was directed to a new salt of the previously known herbicide "dicamba." The Solicitor argued that since both "dicamba"and a particular form of salt cation were known in the art, the dicamba salt formed with the known cation was *prima facie* obvious. The court held that no *prima facie* case for rejection had been made, relying on the large number of species embraced by the prior art genus and the absence of any specific **motivation** to use the particular salt cation with dicamba. 21 U.S.P.Q.2d at 1943. The court specifically rejected the argument that one of skill in the art would have been **motivated** to

use the particular salt cation with dicamba since structurally similar salts had previously been prepared. 21 U.S.P.Q. at 1943-44.

In *Jones,* the prior art salt and the claimed salt had common herbicidal utility. By analogy, even if the genes disclosed in prior art and those used in the claimed combination have common beneficial effects, that alone cannot provide the **motivation** to make and use the instant invention. To reject the present claims because Goldman and Lundquist refer generically to use of all "agronomically significant traits" or "all DNA" amounts to doing away with the well-established patent law principle that, "a claim to a particular species is patentable over the disclosed genus (that is infinite and undefined)." *Id.*

3. Genes Previously Expressed in Dicots Do Not Provide Motivation to Introduce the Same Genes into Monocots such as Corn.

The Answer places reliance on what it terms Appellants' "admissions" as to the scope and content of the prior art. Appellants in no way concede that all of the gene elements set forth in the appealed claims have been expressed in plants other than corn, and/or successfully used in the prior art to achieve a desired transgenic trait. Many of the genes or genetic elements have only been studied by genetic engineering, and not expressed transgenically in a plant. Several of the specified genes have been expressed in plants, but only in plants such as *Arabidopsis* or tobacco that are quite distinct from corn.

An overview of the exemplary references set forth as Brief Exhibits D-L shows the following general categories: 1) Less than one-half of the genes listed in the claims have been

expressed transgenically in a plant. These were limited to transgenic expression in a dicot such as tobacco or *Arabidopsis.* 2) Many of the genes were isolated from other organisms and have not been genetically engineered in plants. 3) Many of the specified genes have been described in various plants such as tobacco, but have not genetically engineered into a transgenic plant.

Some of the claimed transgenic corn species bear genetic elements previously expressed only in dicotyledonous plants such as tobacco, which are far removed from transgenic corn. The distinction between corn and dicots was addressed in *In re Goodman*, 29 U.S.P.Q. 2010 (Fed. Cir. 1993), which found that techniques applicable to dicots were not applicable to monocots absent specific supporting evidence. Due to their significant biological differences, the disclosure of a gene functional in a dicot does not render *prima facie* obvious that gene in the context of transgenic corn. *Id.* Thus, one skilled in the art would not obtain the **motivation** to introduce a gene into a monocotyledonous plant such as corn, merely because the same gene had been introduced and expressed in a dicotyledonous plant like tobacco.

4. Conclusion.

Appellants submit that the issues raised in the Answer with respect to obviousness have been fully addressed in the main Brief and the foregoing Reply. It is submitted that Appellants' have fully demonstrated that the Examiner has failed to make a *prima facie* case of obviousness, based upon a consideration of the prior art and the prevailing case law.

B. Rejection of Claim 50 under 35 U.S.C. § 112, Second Paragraph

The Examiner has introduced a rejection of claim 50, on the basis that it depends from a rejected base claim.

Claim 50 was canceled on the basis that there was no pending claim having an appropriate antecedent basis ("replication vector") for this claim. Thus, this rejection is now moot.

C. Summary and Conclusion

In light of the foregoing comments, Appellants submit that the appealed claims meet the requirements for patentability. Therefore, Appellants respectfully request that the Board reverse each of the rejections.

Respectfully submitted,

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APPENDIX A
CLAIMS ON APPEAL

Claims are as currently amended, including the requested cancellation of claims 50, 53 and 54 filed with this reply brief.

2. Cells obtained from the plant of any one of claims 47 or 60-67, wherein said cells comprise the introduced gene.

3. Progeny of the plant of any one of claims 47 or 60-67, wherein said progeny comprise the introduced gene.

4. Seeds obtained from the plant of claim 3, wherein said seeds comprise the introduced gene.

47. A fertile, transgenic maize plant, the genome of which has been augmented by the introduction of a DNA composition comprising a selectable or screenable marker gene selected from the group of genes consisting of an aequorin gene and a gene encoding a cell wall protein, so that the transgenic plant exhibits one or more phenotypic characteristics that render it identifiable over the corresponding untransformed maize plant which does not comprise said gene, and wherein said gene is transmittable through normal sexual reproduction of the transgenic maize plant to subsequent generation plants.

51. The transgenic maize plant of claim 47, wherein the gene is positioned under the control of a promoter region comprising multiple copies of the 16 bp *ocs* enhancer element.

52. The transgenic maize plant of claim 47, wherein the selectable or screenable marker gene comprises non-expressed DNA.

55. The transgenic maize plant of claim 47, wherein the selectable or screenable marker gene comprises an aequorin gene.

56. The transgenic maize plant of claim 47, wherein the selectable or screenable marker gene comprises a gene encoding a cell wall protein.

57. The transgenic maize plant of claim 56, wherein the selectable or screenable marker gene comprises a gene encoding an HPRG.

58. The transgenic maize plant of claim 47, wherein the coding sequence of the gene is modified to improve expression in maize.

60. A fertile, transgenic maize plant, the genome of which has been augmented by the introduction of a DNA composition comprising a negatively-selectable marker selected from the group of genes consisting of a cytosine deaminase gene; a T-DNA gene 2; an antisense *bar* gene; and an antisense *npt*II gene, so that the transgenic plant exhibits one or more characteristics that render it identifiable over the corresponding untransformed maize plant which does not comprise said marker, and wherein said marker is transmittable through normal sexual reproduction of the transgenic maize plant to subsequent generation plants.

61. A fertile, transgenic maize plant, the genome of which has been augmented by the introduction of a DNA composition comprising an exogenous gene encoding a selected trait, the gene positioned under the control of an inducible or tissue-specific promoter or enhancer comprising an α-tubulin promoter, an *ocs* promoter, an ABA-inducible promoter, or a turgor-inducible promoter, so that the transgenic plant exhibits one or more phenotypic characteristics that render it identifiable over the corresponding untransformed maize plant which does not comprise said gene, and wherein said gene is transmittable through normal sexual reproduction of the transgenic maize plant to subsequent generation plants.

62. A fertile, transgenic maize plant, the genome of which has been augmented by the introduction of a DNA composition comprising a gene encoding a herbicide resistance trait comprising a *bxn* gene, so that the transgenic plant exhibits one or more phenotypic characteristics that render it identifiable over the corresponding untransformed maize plant which does not comprise said gene, and wherein said gene is transmittable through normal sexual reproduction of the transgenic maize plant to subsequent generation plants.

63. A fertile, transgenic maize plant, the genome of which has been augmented by the introduction of a DNA composition comprising a gene encoding an insect resistance trait selected from the group of genes consisting of an oryzacystatin gene; a wheat or barley amylase inhibitor gene; a lipoxygenase gene; an ecdysteroid UDP-glucosyl transferase gene; and a DIMBOA synthetic gene of the *bx* locus, so that the transgenic plant exhibits one or more phenotypic characteristics that render it identifiable over the corresponding untransformed maize plant which does not comprise said gene, and wherein said gene is transmittable through normal sexual reproduction of the transgenic maize plant to subsequent generation plants.

64. A fertile, transgenic maize plant, the genome of which has been augmented by the introduction of a DNA composition comprising a gene encoding a pathogenesis related (PR) protein gene, so that the transgenic plant exhibits one or more phenotypic characteristics that render it identifiable over the corresponding untransformed maize plant which does not comprise said gene, and wherein said gene is transmittable through normal sexual reproduction of the transgenic maize plant to subsequent generation plants.

65. A fertile, transgenic maize plant, the genome of which has been augmented by the introduction of a DNA composition comprising a gene encoding a stress resistance trait selected from the group of genes consisting of a glycerol-3-phosphate acetyltransferase gene; a superoxide dismutase gene; and a glutathione reductase gene, so that the transgenic plant exhibits one or

more phenotypic characteristics that render it identifiable over the corresponding untransformed maize plant which does not comprise said gene, and wherein said gene is transmittable through normal sexual reproduction of the transgenic maize plant to subsequent generation plants.

66. A fertile, transgenic maize plant, the genome of which has been augmented by the introduction of a DNA composition comprising a gene encoding a drought resistance trait selected from the group of genes consisting of a mannitol-1-phosphate dehydrogenase gene; a trehalose-6-phosphate synthase gene; a myoinositol 0-methyltransferase gene; and a Late Embryogenic Protein (LEA) gene, so that the transgenic plant exhibits one or more phenotypic characteristics that render it identifiable over the corresponding untransformed maize plant which does not comprise said gene, and wherein said gene is transmittable through normal sexual reproduction of the transgenic maize plant to subsequent generation plants.

67. A fertile, transgenic maize plant, the genome of which has been augmented by the introduction of a DNA composition comprising a gene encoding a grain composition trait selected from the group of genes consisting of an acetyl-CoA carboxylase gene; an ACP-acyltransferase gene; a β-ketoacyl-ACP synthase gene; an acyl carrier protein gene; a fatty acid desaturase gene; a fatty acid epoxidase gene; a fatty acid hydratase gene; a fatty acid dehydratase gene; a sense or antisense phytoene synthase gene; a sense or antisense phytoene desaturase gene; a sense or antisense lycopene synthase gene; a phytase gene; an ADP-glucose pyrophosphorylase gene; a starch synthase gene; a starch branching enzyme gene; and a sucrose synthase gene, so that the transgenic plant exhibits one or more phenotypic characteristics that render it identifiable over the corresponding untransformed maize plant which does not comprise said gene, and wherein said gene is transmittable through normal sexual reproduction of the transgenic maize plant to subsequent generation plants.